Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Determining the effect of quince fruit extract and apple cider vinegar on glycemic indices in adults with prediabetes: A double blind randomized clinical trial

Protocol summary

Study aim
Determining the effect of fruit extract and apple cider vinegar on glycemic indices in adults with prediabetes.

Design
Controlled, parallel-group, double-blind, randomized trial on 108 patients. Block randomization (block size 6, 18 blocks; allocation to intervention/control). Random sequence generated by a third party using Excel's rand function. Intervention and placebo identically packaged and coded. Principal investigator and patients blinded to allocation. Outcomes assessed by an independent third party not involved in treatment. Unblinding after final analysis.

Settings and conduct
The participants in this study have prediabetes and are selected through a call and referral by the attending physician of Taleghani Hospital Clinic. After explaining the purpose of the study, if desired, patients will refer to the laboratory of the Endocrine Sciences and Research Institute at the specified time. Patients are asked to fast for 12 hours on the day of visiting the clinic.

Participants/Inclusion and exclusion criteria
Inclusion criteria: cooperation, prediabetes, age 20–50, no smoking or alcohol, no specific diet, no weight change in last 3 months, non-pregnant or lactating, BMI 20–30. Exclusion criteria: lifestyle or drug change during trial, unwillingness to consume apple cider vinegar–quince mixture, hypersensitivity to apple cider vinegar, GI disorders (IBS/IBD).

Intervention groups
Patients with prediabetes will be randomly divided into 3 groups (2 intervention groups and 1 control group). In the first group, advise to consume one tablespoon of apple cider vinegar with a glass of water during each meal. In second group, advise to consume one tablespoon of fruit juice during each meal . In the third group, the control group will not receive anything.

Main outcome variables
Blood sugar control

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160822029472N3**
Registration date: **2026-05-11, 1405/02/21**
Registration timing: **prospective**

Last update: **2026-05-11, 1405/02/21**
Update count: **0**

Registration date
2026-05-11, 1405/02/21

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2026-12-22, 1405/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the effect of quince fruit extract and apple cider vinegar on glycemic indices in adults with prediabetes: A double blind randomized clinical trial

Public title
Effect of quince fruit extract and apple cider vinegar on glycemic indices
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate; Having prediabetes; Age between 20 and 50 years; No smoking or alcohol; No special diet; No weight change in the past 3 months; No pregnancy or breastfeeding; BMI between 20 and 30.
Exclusion criteria:
Intention to modify lifestyle or pharmacological therapy over the course of the study Unwillingness to consume the mixture of apple cider vinegar and quince fruit Known allergy or adverse reaction to apple cider vinegar Presence of gastrointestinal diseases (irritable bowel syndrome and inflammatory bowel disease)
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
The design of this study is perfumed block randomization, in which the participants are allocated to intervention and control groups using the Block Randomization method in 18 blocks (in 3 groups) with a Block size of 6. In this study, which will be conducted for 12 weeks, patients with prediabetes will be randomly divided into 3 groups (2 intervention groups and 1 control group). In the first group, it is recommended to consume one tablespoon of apple cider vinegar with a glass of water during each meal (breakfast, lunch, and dinner). In the second group, it is recommended to consume one tablespoon of fruit juice during each meal (breakfast, lunch, and dinner). In the third group, the control group receives nothing. In this study, the principal investigator will not be involved in the randomization process.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, blinding will be done for patients and researchers, and a person outside the research team will be selected to evaluate the results. Randomization will be done by a third person. In this way, patients and study researchers are not aware of the type of groups and the double-blind conditions of the study are maintained. Apple cider vinegar and fruit will be packaged and shipped in such a way that the difference between the two cannot be easily identified. At the end of the study, after the results are determined, the labels will be revealed by a third person and the information will be evaluated.
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Nutrition Research Institute Ethics Committee
Street address
Hafezi Street
City
Tehran
Province
Tehran
Postal code
۱۹۸۱۶۱۹۵۷۳
Approval date
2025-05-18, 1404/02/28
Ethics committee reference number
IR.SBMU.nnftri.Rec.1404.014

Health conditions studied

1

Description of health condition studied
Prediabetes
ICD-10 code
R73.01
ICD-10 code description
Impaired fasting glucose

Primary outcomes

1

Description
Fasting plasma glucose
Timepoint
First, the sixth and twelfth weeks
Method of measurement

Enzymatic colorimetric method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Recommended to consume one tablespoon (5 ml) of apple cider vinegar with a glass of water during each meal (breakfast, lunch, and dinner).
Category
Treatment - Other

2

Description
Intervention group: In the second group, it is recommended to consume one tablespoon of fruit extract (5 ml) during each meal (breakfast, lunch, and dinner).
Category
Treatment - Other

3

Description
Control group: They don't receive anything.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Research Center, Royan Research Institute
Full name of responsible person
Seyed Hosein Davodi
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Royan Center for Diabetes, Obesity and Metabolism, Neda dead end- South Golzar St., Sanaye St., Sayad Shirazi Highway (North)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Afshin Zarghi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No further information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available